Food and Drug Administration, HHS

Maintain adequate water intake during the treatment period.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]

$\begin{array}{ccc} \$\,520.2220d & Sulfadimethoxine-\\ ormetoprim\ tablets. \end{array}$

- (a) Specifications. Each tablet contains 120 milligrams (100 milligrams of sulfadimethoxine and 20 milligrams of ormetoprim), 240 milligrams (200 milligrams of sulfadimethoxine and 40 milligrams of ormetoprim), 600 milligrams (500 milligrams of sulfadimethoxine and 100 milligrams of ormetoprim), or 1200 milligrams (1,000 milligrams of sulfadimethoxine and 200 milligrams of ormetoprim).
- (b) Sponsor. See No. 000069 in $\S 510.600(c)$ of this chapter.
- (c) Conditions of use—(1) Amount. On the first day of treatment, administer 25 milligrams per pound (55 milligrams per kilogram) of body weight. Then follow with a daily dosage of 12.5 milligrams per pound (27.5 milligrams per kilogram) of body weight.
- (2) Indications of use. Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of Staphylococcus aureus and Escherichia coli and urinary tract infections caused by Escherichia coli, Staphlococcus spp., and Proteus mirabilus susceptible to ormetoprim-potentiated sulfadimethoxine.
- (3) Limitations. Continue treatment until patient is asymptomatic for 48 hours, but do not exceed a total of 21 consecutive days. Maintain adequate water intake during the treatment period. Safety in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 48593, Nov. 24, 1989, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 61 FR 46719, Sept. 5, 1996]

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

(a) Chemical name. N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.

- (b) Specifications. Melting point range of 180 °C. to 186 °C.
- (c) Sponsor. See No. 053501 in §510.600(c) of this chapter.
- (d) Related tolerances. See §556.650 of this chapter.
- (e) Conditions of use. It is used as follows:
- (1) Swine—(i) Amount. 1.9 to 3.8 grams per gallon (0.05 percent to 0.1 percent).
- (ii) Indications for use. Treatment of bacterial scours pneumonia enteritis, bronchitis, septicemia accompanying Salmonella cholerasuis infection.
- (iii) Limitations. Administer 3.8 grams per gallon for first day followed by 1.9 grams per gallon for not less than 3 days nor more than 9 days as sodium sulfaethoxypyridazine; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.
- (2) Cattle—(i) Amount. 2.5 grams per gallon (0.066 percent).
- (ii) Indications for use. Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.
- (iii) Limitations. Administer at the rate of 1 gallon per 100 pounds of body weight per day for 4 days; as sodium sulfaethoxypyridazine; do not treat within 16 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after latest treatment must not be used for food.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.2240b Sulfaethoxypyridazine tablets.

- (a) Chemical name. N'-(6-Ethoxy-3-pyridazinyl) sulfanilamide.
- (b) Specifications. Melting point range of 180 $^{\circ}\mathrm{C}$ to 186 $^{\circ}\mathrm{C}.$
- (c) Sponsor. See No. 053501 in $\S510.600$ (c) of this chapter.
- (d) Related tolerances. See §556.650 of this chapter.
- (e) Conditions of use. It is used for cattle as follows:
- (1) Amount. 2.5 or 15 grams per tablet.
- (i) Indications for use. Treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as